PP#4330

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 26 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

**MEMORANDUM:**

SUBJECT: **4F4330.** Cyfluthrin in/on Potatoes. Evaluation of Residue Data and Analytical Methodology. CBTS# 13,416. DP Barcode D200713. MRID#'s 431450-00, 431450-01, 431450-02.

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Miles, Incorporated is requesting the establishment of tolerances for cyfluthrin [cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate] in/on potatoes at 0.01 ppm.

Tolerances for cyfluthrin have previously been established on several commodities at levels ranging from 0.01 to 4 ppm, and are listed in 40 CFR §180.436. Food and feed additive tolerances of 0.05 ppm have also been established as a result of use of cyfluthrin in food/feed handling establishments and are listed in 40 CFR §185.1250 and §186.1250, respectively.

Cyfluthrin is not a reregistration chemical, and therefore is not subject to reregistration review of the current database.

## CONCLUSIONS

1. All product chemistry data requirements for technical grade cyfluthrin and BAYTHROID® 2 have been addressed. No impurities are expected to be present in the TGAI which would cause residue chemistry concerns. All inerts in the end use product have been cleared for agricultural use.

2. The nature of the residue in plants and animals is adequately understood. The residue to be regulated is parent cyfluthrin.

3. Adequate analytical methods are available for the enforcement of tolerances in plant and animal commodities. These methods have been forwarded to FDA for inclusion in PAM II. Cyfluthrin can also be recovered using FDA multiresidue methodology. Adequate recoveries were obtained down to 0.01 ppm for potato tubers in this petition using a slightly modified version of the PAM II method.

4. Geographical representation of residue data is adequate for the proposed use on potatoes.

5. Residue data on potatoes show that residues were $<0.01$ ppm in the treated and control samples after cyfluthrin treatment at 0 and 3 day PHI.

6. CBTS concludes that the proposed tolerance of 0.01 ppm in/on potatoes is adequate.

7. The potato processing study showed that residues of cyfluthrin in/on potatoes and its processed commodities (potato chips and potato granules) were below the detection limit ($<0.005$ ppm). No residue data were sent for potato wet or dry peel.

8. CBTS concludes that based on the fact that at an exaggerated rate (6X) nondetectable residues ($<0.005$ ppm) were found in the rac and processed commodities (chips and granules), no residue data need to be submitted for potato dry or wet peel. We expect residues in this commodity to be below those in the rac. Therefore, no food/feed additive tolerances need to be proposed for potatoes.

9. An International Residue Limit (IRL) Status Sheet is appended to this review. There are no Codex, Canadian or Mexican Limits established for cyfluthrin on potatoes. Therefore, no compatibility problems exist.

## RECOMMENDATION

TOX considerations permitting, CBTS recommends that the proposed tolerance for residues of cyfluthrin in/on potatoes at 0.01 ppm be established.

## DETAILED CONSIDERATIONS

## PRODUCT CHEMISTRY

The manufacturing process of technical grade cyfluthrin has been previously described and found to be acceptable (see PP# 4F3046, 5/18/84 memo of K. Arne). None of the actual or theoretical impurities are expected to cause residue concerns.

The end use product proposed for use on potatoes is Baythroid® 2 Emulsifiable Pyrethroid Insecticide (EPA Reg. No. 3125-351), which contains 25% cyfluthrin and 75% inerts. This formulation contains 2 lb ai/gal. Since the product has already been registered, it is assumed that all inerts have been cleared by RD for use in agricultural pesticides.

## PROPOSED USE

To control potato leafhopper apply 0.8 to 1.6 fl. oz/A (0.0125-0.025 lbs. ai/A). To control cabbage looper, colorado potato beetle, european corn borer, flea beetles, potato tuberworm, potato psyllid, tarnish plant bug, and aphids apply 1.6 to 2.8 (0.025-0.044 lbs. ai/A). Apply specified dosage per acre by air or ground equipment in sufficient water (minimum 2 gallons for aerial application) to allow for thorough coverage of foliage. Allow at least 5 days between applications. A total of 6 applications for a maximum of 16.8 fluid ounces (0.26 lbs. ai) may be applied per acre per crop season. Applications may be made up to and including day of harvest.

## NATURE OF THE RESIDUE

### Plants

No plant metabolism studies were submitted with this petition. However, acceptable metabolism studies with radiolabeled cyfluthrin have been conducted in cotton and soybeans (PP#3G2976), potatoes (PP#4F3046), apples (PP#5G3307), wheat and tomatoes (PP#9F3731). Data from these studies indicate that the major residue detected is the parent cyfluthrin, which metabolizes slowly with little translocation. Several metabolites have also been reported, but the parent compound is considered to be the residue of concern.

CBTS concludes that the nature of the residue in plants is adequately understood. The residue of concern is the parent cyfluthrin. Tolerances for residues in/on plant commodities are presently expressed in terms of cyfluthrin *per se*.

Animals

No new animal metabolism studies were submitted with this petition. However, acceptable metabolism studies with radiolabeled cyfluthrin have been submitted for dairy cows, laying hens, and rats in conjunction with PP#4G2976. For a detailed review, see 2/23/84 memo, R. Loranger; for a summary, see 11/17/89 memo, H. Fonouni, PP#9F3731/9H5574.

In the cow metabolism study, a dairy cow was dosed with [phenoxy-$^{14}$C]cyfluthrin at 33 ppm for five consecutive days. The parent cyfluthrin constituted the major radioactive residue in various tissues and milk (56-100% of TRR).

Potato commodities are not poultry feed items. Therefore, the metabolism of cyfluthrin in poultry is irrelevant to this petition.

CBTS concludes that, for the purpose of the current petition, the nature of the residues in animals is adequately understood. The residue of concern is cyfluthrin. Tolerances for residues in animal commodities (milk, and fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep) are presently expressed in terms of cyfluthrin *per se*.

## ANALYTICAL METHODOLOGY

Analytical methodology suitable for the enforcement of cyfluthrin tolerances in plant and animal commodities is available. The methodology was successfully validated by EPA's Beltsville lab in support of tolerances on cottonseed (see PP# 4F3046). For crops the sample is ground and extracted with organic solvents, and cleaned up using florisil column chromatography. Residues are quantified by gas chromatography equipped with an electron capture detector. For meat, milk and eggs, the methodology also involves extraction with organic solvents and additional partitioning with various solvents to remove polar and nonpolar interferences, followed by final cleanup using florisil column chromatography. Residues are quantified by gas chromatography equipped with an electron capture detector. Limits of quantification are as low as 0.01 ppm, but vary according to the commodity (see also 5/5/94 memo of J. Morales, PP# 3F4204). Validation data for potatoes are discussed in the next two sections of this review. The methods were forwarded to FDA for inclusion in PAM II in March 1988, but have not yet been published.

Cyfluthrin has also been analyzed using the FDA multiresidue protocols. According to the FDA Pestrack database, it can be completely (>80%) recovered using protocol A (see also 12/4/87 memo of M. Bradley, PP# 4F3046).

## RESIDUE DATA

Residue data reflecting application of cyfluthrin to potatoes appear in the following report:

> "Baythroid® - Magnitude of the Residue on Potatoes"; W. L. Leslie; 12/22/88; Performing Laboratories were Morse Laboratories, Sacramento, CA and Mobay Corporation, Agricultural Chemicals Division, Stilwell, KS (MRID# 431450-01).

Eleven field trials on potatoes were conducted in 1983. The field trials were conducted in ME, OR, NY, ID, ND, WI, MN, IN, CO, FL, and WA. According to Agricultural Statistics, 1988, these states represent nearly 76% of the potato production in the U.S. Six foliar applications of Baythroid® 2 EC were made to potato plants at the rate of 50 g ai/ha/application (0.044 lbs. ai/A). Applications were made utilizing ground equipment at 5 to 9 days intervals with spray volumes ranging from 13 to 130 gallons per acre. Samples of whole potatoes (tubers) were collected at 0, 3, 7, 14, and 21 days after the last application. After collection, samples were frozen and shipped to Morse Laboratories for processing studies and to Mobay Corporation for field trial analyses.

CBTS concludes that geographic representation of residue data is adequate for the proposed use on potatoes.

Cyfluthrin residues were shown to be stable (~65-120% recovery) in/on apples, cantaloupe, corn, corn oil, corn starch, cucumbers, oranges, orange juice, dry orange pulp, peanut shells, potato tubers, potato chips, potato granules, dry potato peels, rice hulls, tomatoes, wheat bran, wheat flour, and wheat dust under frozen storage conditions (-23 °C) for up to 7 months. Cyfluthrin is stable (~65-120% recovery) in/on wet potato peels, rice grain, and wheat grain under frozen storage conditions (-23 °C) for up to 3 months, 1 month, and 3 months, respectively (J. Morales memo of 5/5/94, PP#3F4204/3H5670). Potato samples were analyzed for cyfluthrin residues up to almost 4 months after sampling. Maximum interval between extraction and analyses was 7 days.

Whole potatoes were homogenized, and residue levels determined using a slightly modified version of method No. 85823, which is the enforcement methodology described above. Briefly, the analytical procedure consisted of sample extraction with methanol/water (4:1), followed by a liquid-liquid partition with chloroform/acetone (2:1), and a final cleanup using a florisil column. Quantitation was performed by gas chromatography utilizing a Coulsen Cl Cell Detector. The limit of detection was 0.01 ppm. The limit of quantitation (LOQ) was 0.05 ppm. To validate the results of the analyses on potatoes, control samples were fortified at the level of 0.05 ppm (4 replicates). Recoveries ranged from 84% to 90%. Concurrent recovery samples in potatoes were run with each treated sample set. Submitted chromatograms show well resolved peaks in support of these data. CBTS further notes that adequate recoveries were obtained for fortifications down to 0.01 ppm for tubers used in the

processing study (see next section). Therefore, the LOQ for potatoes can be considered to be 0.01 ppm.

Residue data on potatoes show that residues were <0.01 ppm in the treated and control samples after cyfluthrin treatment at 0 and 3 day PHI.

CBTS concludes that the proposed tolerance of 0.01 ppm in/on potatoes is adequate. Therefore, TOX considerations permitting, CBTS recommends that the proposed tolerance for residues of cyfluthrin in/on potatoes at 0.01 ppm be established.

## PROCESSED COMMODITIES

Residues resulting from the processing of potatoes has been submitted in the following report:

> "Cyfluthrin (2EC Formulation) - Magnitude of the Residue Study in Potato Processed Products"; J.L. Wiedman and J. E. Jablonski; 9/10/90. Performing Laboratory was Ricerca Inc., Painesville, OH (MRID# 431450-02).

A field trial was conducted during 1989 in Washington. Six foliar broadcast applications of Baythroid 2EC were made at a rate of 4 ounces ai/A (0.25 lbs. ai/A, 6X). The time period between applications ranged from 4 to 10 days. Potatoes were harvested on the same day as the final treatment. The potatoes were processed into granules and chips (the complete processing procedure is given on page 36 of the report). Cyfluthrin residues were determined using the same enforcement methodology described above with minor modifications. The petitioner stated that the limit of quantitation was 0.01 ppm and the limit of detection was 0.005 ppm. Control samples showed no detectable residues.

Samples were analyzed for cyfluthrin residues within 8 months after sampling. Maximum interval between extraction and analysis was 7 days. The petitioner submitted storage stability on potato and its processed commodities (dry peels, granules, wet peels, and chips). The data showed that these commodities were stable under frozen conditions for periods up to 7 months.

Potato tubers were validated at the level of 0.01 ppm, 0.02 ppm, and 0.05 ppm with a recovery range of 80% to a 100%. Potato chips were validated at the same fortification levels with a recovery range of 70% to 120%. Potato granules were validated at the same fortification levels with a recovery range of 76% to 120%.

The potato processing study showed that residues of cyfluthrin in/on potatoes and its processed commodities (potato chips and potato granules) were below the detection limit (<0.005 ppm). No residue data were sent for potato wet or dry peel.

CBTS concludes that based on the fact that at an exaggerated rate (6X) nondetectable residues (<0.005 ppm) were found in the rac and processed commodities (chips and granules), no residue data need to be submitted for potato dry or wet peel. We expect residues in this commodity to be below those in the rac. Therefore, no food/feed additive tolerances need to be proposed for potatoes.

## MEAT, MILK, POULTRY AND EGGS

Tolerances for residues of cyfluthrin on cottonseed at 1.0 ppm and hops at 4.0 ppm have been established. Thus the proposed use on potatoes will be covered by the existing milk and meat tolerances.

## OTHER CONSIDERATIONS

An International Residue Limit (IRL) Status Sheet is appended to this review. There are no Codex, Canadian or Mexican Limits established for cyfluthrin on potatoes. Therefore, no compatibility problems exist.

Attachment: International Residue Limit Status Sheet

cc: RF, Circu., José J. Morales, E. Haeberer, PP#4F4330
7509C: Reviewer (JJM): CM#2: Rm 804-B: 305-5010: typist (JJM): 5/22/95
RDI: E. Haeberer (5/24/95): R. Loranger (5/25/95): E. Zager (5/26/95)

I Nieves 5/19/95

Attachment:

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INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Cyfluthrin

CODEX NO. 157

CODEX STATUS:

[M] No Codex Proposal
Step 6 or Above (on potato)

Residue (if Step 8): _____

cyfluthrin

| Crop(s) | Limit (mg/kg) |
|---|---|

PROPOSED U.S. TOLERANCES:

Petition No. 4F4330

DEB Reviewer J. Morales

Residue: Cyfluthrin

| Crop(s) | Limit (mg/kg) |
|---|---|
| potatoes | 0.01 |

CANADIAN LIMITS:

[M] No Canadian Limit

Residue: _____

| Crop(s) | Limit (mg/kg) |
|---|---|

MEXICAN LIMITS:

[M] No Mexican Limit

Residue: _____

| Crop(s) | Limit (mg/kg) |
|---|---|

NOTES

Form Revised 1989